

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Confirmation No. : 3538  
Appln. No. : 10/719,734  
Applicant : Solomon S. Steiner et al.  
Filed : 11/21/2003  
TC/A.U. : 1616  
Examiner : Henry J. Alstrom-Acevedo  
Docket No. : 1951300-00060  
Customer No. : 45200  
Title : A Method for Delivery of Monomeric or Dimeric Insulin Complexed to Diketopiperazine Microparticles

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**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. 1.97**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further requests that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☐ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);

- OR -

- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;  
- OR
- ☐ (3) It is being filed in compliance with 37 C.F.R. § 1.97 (e)(1) and each item of information contained in the information disclosure statement was first cited in a communication from the International Search Report not more than three months prior to the filing of the information disclosure statement.  
- OR
- ☐ (4) It is being filed in compliance with 37 C.F.R. § 1.97 (e)(1) and each item of information contained in the information disclosure statement was first cited in a communication from the International Search Report more than three months prior to the filing of the information disclosure statement, but before the mailing date of the first Office Action;  
- OR
- ☐ (5) It is being filed before the mailing date of the first Office Action on the merits;  
- OR
- ☐ (6) It is being filed with copies of the Information Disclosure Statement(s) from the U.S. Parent application;  
- OR -
- ☐ (7) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.
- ☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a certification as specified in §1.97(e) provided concurrently herewith;  
- OR -
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- ☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).
- ☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☒ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.  
    — OR —  
☐ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.  
    — AND/OR —  
☐ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Forms PTO/SB/08A-B are enclosed in accordance with 37 CFR §1.98(a)(2).  
    — AND/OR —  
☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).
- ☒ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☐ Pursuant to 37 CFR §198(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.  
    — AND/OR —  
☒ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.  
    — AND/OR —  
☐ A copy of the European Search Report indicating the relevance of the non-English language reference(s) is provided herewith
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☐ *No Fees Due.* Applicants believe no fee is due with this filing, however, if it is deemed that a fee is due, the Director is hereby authorized to charge any fees or credit any overpayments to Deposit Account No. 50-3207.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-3207.

Respectfully submitted,

Dated: 31 October 2008

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